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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,727	12/26/2001	Sukanta Banerjee	4364-4005	1379

23973 7590 08/24/2006

DRINKER BIDDLE & REATH  
ATTN: INTELLECTUAL PROPERTY GROUP  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/034,727	<b>Applicant(s)</b> BANERJEE ET AL.	
	<b>Examiner</b> Nelson Yang	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 83-86, 88, 89 and 91-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 83-86, 88, 89 and 91-96 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 83-86, 88-89, 91-96 are currently pending.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 83-86, 88, 89, 91-96 rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al [US 6,887,701].

With respect to claim 92, Anderson et al teach a method comprising attaching agents of interest to particles that are suspended in a polymerizing medium, which is used to fill tubules used to make array bundles and arrays (column 3, lines 57-61). The particles may further be labeled with different fluorescently labeled analytes for competition assays, where each specific antibody binds to one of the fluorescently labeled analytes (first form of encoding) (column 14, lines 15-32). More specifically, Anderson et al. teach an embodiment where antibodies were immobilized on particulate supports (Poros G) (column 26, line 66 – column 27, line 10), followed by binding with HSA and Tf protein labeled with fluorescein isothiocyanate (column 27, lines 60-65). In addition, the fibers or the gelling material may also contain different dyes (column 22, lines 15-18), thus allowing beads in different fibers to be identified (alternative form

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of encoding). The fibers may have rectangular and square cross sections (the two opposing planar surfaces) (column 6, lines 6-15). The polymerizing medium may be polymerized by ultraviolet light using a catalyst (column 10, lines 62-67).

4. With respect to claim 83, Anderson et al teach the use of fluorescent labels (column 14, lines 15-32), which would be color.

5. With respect to claims 85-86, Anderson et al teach immobilized antibodies (proteins) (column 14, lines 23-25)

6. With respect to claim 89, Anderson et al teach 5 micron diameter particles (column 27, lines 20-32).

7. With respect to claim 93, the open ends of the capillaries may be sealed against a flat plate (column 22, lines 32-35) or a solid phase material may be attached to one end of the bundle (column 22, lines 45-50)

8. With respect to claim 94, the sides of the fibers (column 3, lines 57-61, column 6, lines 6-15)) would define the thickness of the gel embedded particle assembly.

9. With respect to claim 95, the beads suspended in the polymer must be capable of binding to analytes in a multiple competition assay (column 14, lines 25-32) such as proteins (column 14, lines 15-20), so therefore the polymer is permeable to macromolecules.

10. With respect to claim 96, the gel assembled bead assembly is self supporting, as the solid phase material is not required for the bundle (it is used in an alternative embodiment) (column 22, lines 45-52).

11. Claim 84 is rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al [US 6,887,701] in light of Domschke et al [US 6,897,271].

With respect to claim 84, Anderson et al teach that the polymer may be comprised of acrylamide gels (column 10, lines 50-67), which one of ordinary skill in the art would know the be hydrophilic, as evidenced by Domschke et al (column 2, lines 63-68).

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 88 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al [US 6,887,701] in view of Bryan et al [US 6,458,547].

With respect to claim 88, Anderson et al teach a method comprising attaching agents of interest to particles that are suspended in a polymerizing medium, which is used to fill tubules used to make array bundles and arrays (column 3, lines 57-61). The particles may further be labeled with different fluorescently labeled analytes for competition assays, where each specific antibody binds to one of the fluorescently labeled analytes (first form of encoding) (column 14, lines 15-32). More specifically, Anderson et al. teach an embodiment where antibodies were immobilized on particulate supports (Poros G) (column 26, line 66 – column 27, line 10), followed by binding with HSA and Tf protein labeled with fluorescein isothiocyanate (column 27, lines 60-65). In addition, the fibers or the gelling material may also contain different dyes (column 22, lines 15-18), thus allowing beads in different fibers to be identified (alternative form of encoding). The fibers may have rectangular and square cross sections (the two opposing

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planar surfaces) (column 6, lines 6-15). The polymerizing medium may be polymerized by ultraviolet light using a catalyst (column 10, lines 62-67). Anderson et al further teach that a solid phase material (substrate) may be attached to one end of the bundle (column 22, lines 45-50). Anderson et al do not teach that the solid phase material comprises a silicon chip.

Bryan et al, however, teach the use of silicon chips (column 14, lines 14-21, 45-50), and further teach that the chip is adaptable for use in an array format for the detection and identification of agents in a biological sample with the device (column 5, lines 20-25), using circuits for integrating the output data signals and accumulating them, and further generating an output device signal, in order to generate visible indicia related to the presence of the analytes (column 5, lines 45-55).

Therefore, it would have been obvious to one of ordinary skill in the art for the solid phase material to be a silicon chip in the device of Anderson et al et al, as suggested by Bryan et al, in order to adapt the device for use in the detection and identification of analytes and generation of visible indicia related to the presence of the analytes.

14. Claim 91 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al [US 6,887,701] in view of Walt et al [US 6,327,410].

With respect to claim 91, Anderson et al teach a method comprising attaching agents of interest to particles that are suspended in a polymerizing medium, which is used to fill tubules used to make array bundles and arrays (column 3, lines 57-61). The particles may further be labeled with different fluorescently labeled analytes for competition assays, where each specific antibody binds to one of the fluorescently labeled analytes (first form of encoding) (column 14, lines 15-32). More specifically, Anderson et al. teach an embodiment where antibodies were

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immobilized on particulate supports (Poros G) (column 26, line 66 – column 27, line 10), followed by binding with HSA and Tf protein labeled with fluorescein isothiocyanate (column 27, lines 60-65). In addition, different fibers or the gelling material in different fibers may also contain different dyes (column 22, lines 15-18), thus allowing beads in different fibers to be identified (alternative form of encoding). The fibers may have rectangular and square cross sections (the two opposing planar surfaces) (column 6, lines 6-15). The polymerizing medium may be polymerized by ultraviolet light using a catalyst (column 10, lines 62-67). Anderson et al further teach silica, cellulose, Sepharose beads, polystyrene (solid, porous and derivitized) beads, controlled-pore glass, gel beads, sols, biological cells, viruses, subcellular particles. Anderson et al fail to specifically teach magnetic beads.

Walt et al, however, teach that beads can be made from a variety of compositions including, but not limited to, plastics, ceramics, glass, polystyrene, methylstyrene, acrylic polymers, paramagnetic materials, thoria sol, carbon graphited, titanium dioxide, latex or cross-linked dextrans such as Sepharose, cellulose, nylon, cross-linked micelles and Teflon (column 7, lines 20-30).

Therefore, since Walt et al shows that beads made from paramagnetic materials and polystyrene are equivalent structures known in the art, because these two beads were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute paramagnetic beads for polystyrene beads

### ***Response to Arguments***

15. Applicant's arguments filed June 6, 2006 have been fully considered but they are not persuasive. More specifically, applicant's argument that Anderson et al. do not teach encoded

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beads, but instead teach binding to a “solid support” or a “gel” is not found persuasive. While it is agreed that Anderson et al. teach binding of a labeled analyte to a “solid support”, the Office believes that the “solid support” refers to the particles or beads themselves, as shown in column 26-28, example 1. Applicant also argues that Anderson et al. in essence teach a array of antibodies on a surface, where one knows which antibody is at which location based on their position. While the Office does not disagree with this statement, the Office also notes that the antibodies are bound to particles embedded in agarose in sectioned fibers at each position (columns 26-28, example 1), and that labeled analytes would bind to the antibodies in an assay, thus creating the encoded beads. While the Office acknowledges that Anderson et al. is directed more toward determining bound analytes, and uses the fluorescence to do so, the Office also notes that the steps would also result in encoded beads, where beads with different biomolecules will be differently encoded with different labels. In addition, Anderson et al. teach an alternative form of encoding the beads, namely that different fibers or the gelling material in different fibers may also contain different dyes (column 22, lines 15-18), thus allowing beads in different fibers to be identified. Since applicant does not disclose how the beads are encoded with the labels, both of these methods who constitute a means of encoding the beads and would thus read upon the instant claims.

For these reasons, applicant’s arguments are not found persuasive.

### ***Conclusion***

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Nelson Yang  
Patent Examiner  
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LONG V. LE 08/17/08  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600